UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NELSON GALLEGO, as Administrator of the Estate of JILLIAN ROSE CASTRO FIGUEROA,

Plaintiff,

v.

TANDEM DIABETES CARE, INC.,

Defendant.

MEMORANDUM & ORDER
24-CV-146 (MKB)

MARGO K. BRODIE, United States District Judge:

Plaintiff Nelson Gallego, as administrator of the estate of Jillian Rose Castro Figueroa ("Decedent"), commenced the above-captioned action against Defendant Tandem Diabetes Care, Inc., in the Supreme Court of the State of New York, Queens County, on December 13, 2023, asserting claims of strict products liability based on manufacturing defect, negligent defective design, negligence, strict products liability based on failure to warn, breach of implied warranty of merchantability, and wrongful death under New York law arising out of Decedent's use of an insulin pump that Defendant designed and manufactured. (Notice of Removal ¶¶ 1–2, 4, Docket Entry No. 1; Compl. ¶¶ 18–62, annexed to Notice of Removal as Ex. A, Docket Entry No. 1-1.) On January 8, 2024, Defendant removed the case to the Eastern District of New York invoking diversity jurisdiction. (*Id.* ¶ 9.) On February 15, 2024, Plaintiff filed an Amended Complaint stating the same claims and adding more factual allegations. (*See* Am. Compl., Docket Entry No. 15.)

On April 12, 2024, Defendant moved to dismiss the Amended Complaint on preemption grounds and for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil

Procedure, and Plaintiff opposed the motion.[1] For the reasons explained below, the Court grants Defendant's motion and dismisses Plaintiff's claims for strict products liability based on manufacturing defect, negligent design defect, negligence, strict products liability based on failure to warn, and breach of implied warranty of merchantability on preemption grounds and Plaintiff's wrongful death claim for failure to state a claim.

I. Background

a. Regulatory scheme

The Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 360c *et seq.*, established three regulatory classes for medical devices with varying levels of Food and Drug Administration ("FDA") oversight of devices "based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996); *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 108 (2d Cir. 2006) (quoting 21 U.S.C. § 360c(a)(1)), *aff'd*, 552 U.S. 312 (2008). Class I devices present the least risk, can be marketed without FDA approval, and are subject only to "'general controls' that cover all medical devices." *Riegel*, 451 F.3d at 108 (quoting 21 U.S.C. § 360c(a)(1)(A)). Class II devices may also be marketed without FDA approval but in addition to general controls, may be subject to "special controls" such as "performance standards" and "postmarket surveillance." 21 U.S.C. § 360c(a)(1)(B); *Riegel*, 451 F.3d at 109. Class III devices are intended "for a use in supporting or sustaining human life

[1] (Def.'s Mot. to Dismiss ("Def.'s Mot."), Docket Entry No. 21; Def.'s Mem. in Supp. of Def.'s Mot. ("Def.'s Mem."), Docket Entry No. 21-1; Pl.'s Opp'n to Def.'s Mot. ("Pl.'s Opp'n"), Docket Entry No. 24; Def.'s Reply in Supp. of Def.'s Mot. ("Def.'s Reply"), Docket Entry No. 25.) On August 5, 2024, Defendant filed a notice of supplemental authority to which Plaintiff responded. (Def.'s Notice of Suppl. Auth. ("Def.'s First Notice"), Docket Entry No. 26; Pl.'s Resp. to Def.'s First Notice, Docket Entry No. 27.) Defendant filed a second notice of supplemental authority on August 8, 2024. (Def.'s Notice of Suppl. Auth. ("Def.'s Second Notice"), Docket Entry No. 28.)

or . . . preventing impairment of human health" or "present[] a potential unreasonable risk of illness or injury," 21 U.S.C. § 360c(a)(1)(C)(ii-iii), and "lesser controls are not clearly sufficient to assure their safety and effectiveness." *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 233 (2d Cir. 2021).

Class III devices are "the most stringently regulated," *Glover*, 6 F.4th at 233, and are subject to a "lengthy and rigorous" pre-market approval ("PMA") process, *Riegel*, 451 F.3d at 109 (citing *Lohr*, 518 U.S. at 477). As part of the PMA process, device manufacturers "present to the FDA information about the device's safety and effectiveness, as well as proposed labeling." *Glover*, 6 F.4th at 233 (citing § 360e(c)(1)). The FDCA and its implementing regulations authorize the FDA to impose "post-approval conditions" on Class III devices and withdraw approval if a manufacturer fails to comply with the conditions or FDA's regulations. *Glover*, 6 F.4th at 233 (citing 21 C.F.R. §§ 814.80, 814.82). Manufacturers of approved Class III devices must secure FDA approval "before making any change to the device that would 'affect[] safety or effectiveness.'" *Id.* (alteration in original) (quoting 21 U.S.C. § 360e(d)(5)(A)(i)). A new medical device defaults to Class III and may only avoid the PMA process if the FDA determines through de novo review that the device meets the Class I or Class II criteria or confirms the device is "substantially equivalent" to a pre-existing device. 21 U.S.C. § 360c(f); *Koublani v. Cochlear Ltd.*, No. 20-CV-1741, 2021 WL 2577068, at *2 (E.D.N.Y. June 23, 2021).

b. Factual allegations

At all relevant times, Decedent was a resident of Queens County, New York,[2] (*see* Am. Compl. ¶ 3), and therefore, pursuant to 28 U.S.C. § 1332(c)(2),[3] Plaintiff is deemed a citizen of

[2] The Court assumes the truth of the factual allegations in the Amended Complaint for the purpose of deciding Defendant's motion.

[3] "[T]he legal representative of the estate of a decedent shall be deemed to be a citizen only of the same State as the decedent . . . ." 28 U.S.C. § 1332(c)(2).

New York. Defendant is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in San Diego, California. (*Id.* ¶ 4.) Defendant sells, markets, and promotes its products to consumers in the State of New York and derives substantial revenue from goods sold and used within the State of New York. (*Id.* ¶ 8.)

i. Defendant's t:slim X2 insulin pump

During the relevant time period, Defendant designed, manufactured, distributed, and sold the model t:slim X2 insulin pump ("X2 Pump"), which "delivers a basal rate of insulin" based on user profile settings and a Dexcom continuous glucose monitoring ("CGM") sensor that "measures the user's glucose levels and adjusts insulin delivery accordingly." (*Id.* ¶¶ 10–11, 39, 52.) Defendant equipped the X2 Pump with alarms to notify users of drive train malfunctions and certain other types of failures, and advertised it as a smaller, slimmer model of insulin pump. (*Id.* ¶¶ 15–16.)

The X2 Pump is a Class III medical device subject to the FDA's PMA process, pursuant to which Defendant must seek FDA approval for "any changes to design specifications, manufacturing process, labeling, or other attributes that would affect the product's safety or effectiveness"; "comply with multiple failure modes, including in anticipation of the potential that the pump may be dropped"; and be "subject to certain voluntary standards . . . including a drop test for infusion pumps." (*Id.* ¶¶ 11–14.) From at least July of 2020 through January of 2021, at least thirty-seven records from Defendant addressing "patient impact" described a mechanical problem related to the X2 Pump's cartridges. (*Id.* ¶ 35.)

ii. Decedent's use of the X2 Pump

Defendant issued an X2 Pump to Decedent, a diabetic who depended on the device for CGM and insulin administration. (*Id.* ¶¶ 19, 40, 54.) On January 21, 2022, at approximately 8:24 A.M., Decedent received the following warning message from her X2 Pump, "Alarm 20 /

cartridge alarm," indicating that the X2 Pump could not load the insulin cartridge. (*Id.* ¶ 20.) As a result, all insulin delivery to Decedent stopped. (*Id.* ¶ 21.)

At approximately 8:42 A.M., Decedent called Defendant and spoke with a customer support representative. (*Id.* ¶ 22.) Decedent was not at home and did not have another cartridge with her. (*Id.* ¶ 23.) The customer support representative told Decedent to go home to get a new cartridge and that they would follow-up with her at approximately 9:30 A.M. (*Id.* ¶ 24.) The representative did not tell Decedent to call 911 or seek medical care. (*Id.* ¶ 25.) At approximately 9:35 A.M. and 9:59 A.M., the same customer support agent called Decedent, but she did not answer either call. (*Id.* ¶¶ 26–27.) Despite the cartridge being full of insulin, no insulin was dispensed to Decedent from 8:24 A.M. onward on January 21, 2022. (*Id.* ¶ 29.) Decedent suffered severe emotional distress and anxiety and symptoms associated with rapid blood glucose changes and was found dead in her residence the same day. (*Id.* ¶¶ 29, 50.)

Following Decedent's death, Defendant inspected her X2 Pump and "formulated" a report stating that (1) the device was unable to complete the cartridge load sequence, indicating that the X2 Pump's drive train was operating outside of specifications; (2) the X2 Pump's alarm was triggered on January 21, 2022 by insufficient drive train force within the motor and the X2 Pump sensing the motor was not moving; (3) the alarm warning indicated that a new cartridge should be installed; and (4) physical examination of the device showed multiple dents consistent with the X2 Pump having been dropped. (*Id.* ¶¶ 30–31.) Plaintiff contends that had the X2 Pump been "manufactured with thicker, more stable materials, so as to adequately hedge for the possibility that the pump would be dropped or other errors would be prevented, the cartridge could have been allowed to load and dispense properly," thus avoiding Decedent's "injuries and death." (*Id.* ¶ 32.)

II. Discussion

a. Standard of review

In reviewing a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court "must construe [the Complaint] liberally, accepting all factual allegations therein as true and drawing all reasonable inferences in the plaintiff['s] favor." *Sacerdote v. N.Y. Univ.*, 9 F.4th 95, 106–07 (2d Cir. 2021) (citing *Palin v. N.Y. Times Co.*, 940 F.3d 804, 809 (2d Cir. 2019)); *see also Vaughn v. Phoenix House N.Y. Inc.*, 957 F.3d 141, 145 (2d Cir. 2020) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002)). A complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Bacon v. Phelps*, 961 F.3d 533, 540 (2d Cir. 2020) (quoting *Twombly*, 550 U.S. at 570). "A claim is plausible 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Matson v. Bd. of Educ.*, 631 F.3d 57, 63 (2d Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *see also Roe v. St. John's Univ.*, 91 F.4th 643, 651 (2d Cir. 2024) (quoting *Matson*, 631 F.3d at 63); *Cavello Bay Reinsurance Ltd. v. Shubin Stein*, 986 F.3d 161, 165 (2d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). Although all allegations contained in the complaint are assumed to be true, this tenet is "inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678; *Roe*, 91 F.4th at 651 ("Although all factual allegations contained in the complaint are assumed to be true, this rule does not extend 'to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.'" (quoting *Iqbal*, 556 U.S. at 678)).

b. The relevant device is the Class III "model t:slim X2 insulin pump"

The parties dispute which specific device is at issue in this case. Plaintiff alleges that Decedent used the "model [t]:[s]lim X2 insulin pump" that received PMA as a Class III device.

(*See* Pl.'s Opp'n 8, 10, 13; *see* Am. Compl. ¶¶ 10–11.)

Defendant asserts that the device at issue is the "t:slim X2 insulin pump with Control-IQ technology" ("Control-IQ X2 Pump") that the FDA cleared as a Class II device with special controls under its "De Novo premarket review pathway." (Def.'s Mem. 1–2; Def.'s Reply 1.) Defendant suggests that "[t]he Court may take judicial notice" of FDA documents that it provides in support of its assertion. (Def.'s Mem. 1 n.1, 1–5.)

"In considering a [Rule 12(b)(6)] motion to dismiss for failure to state a claim, 'the district court is normally required to look only to the allegations on the face of the complaint,'" but "may consider documents that 'are attached to the complaint,' 'incorporated in it by reference,' 'integral' to the complaint, or the proper subject of judicial notice." *United States v. Strock*, 982 F.3d 51, 63 (2d Cir. 2020) (quoting *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007)). "If, however, there is a dispute as to the relevance, authenticity, or accuracy of the documents relied upon, the district court may not dismiss the complaint with those materials in mind." *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 231 (2d Cir. 2016); *see also Oberlander v. Coinbase Glob. Inc.*, No. 23-184, 2024 WL 1478773, at *4 (2d Cir. Apr. 5, 2024) ("emphasizing that 'even if a document is integral to the complaint, it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document' and '[i]t must also be clear that there exist no material disputed issues of fact regarding the relevance of the document'" (alteration in original) (quoting *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010))); *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 106 (2d Cir. 2021) (quoting same); *United States v. Persad*, 607 F. App'x 83, 84 (2d Cir. 2015) ("'A court should not' take judicial notice of a fact 'that is an essential part of a party's case unless the fact is clearly beyond dispute.'" (quoting *Pina v. Henderson*, 752 F.2d 47, 50 (2d Cir. 1985))). The "no dispute"

requirement "has been interpreted strictly: even implicit, conclusory, contradictory, or implausible objections to the authenticity or accuracy of a document render consideration impermissible." *Nw. Biotherapeutics, Inc. v. Canaccord Genuity LLC*, No. 22-CV-10185, 2023 WL 9102400, at *8 (S.D.N.Y. Dec. 29, 2023) (quoting *Savides v. United Healthcare Servs., Inc.*, No. 18-CV-4621, 2019 WL 1173008, at *2 (S.D.N.Y. Mar. 13, 2019)); *Fabi v. Prudential Ins. Co. of Am.*, No. 21-CV-4944, 2022 WL 5429520, at *3 (E.D.N.Y. Aug. 29, 2022) (quoting *Grant v. Abbott House*, No. 14-CV-8703, 2016 WL 796864, at *2 (S.D.N.Y. Feb. 22, 2016)); *Fine v. ESPN, Inc.*, 11 F. Supp. 3d 209, 221–22 (N.D.N.Y. 2014) (collecting cases); *see also, e.g.*, *Glob. Network Commc'ns., Inc. v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006) (finding reversible error where the district court considered defendant's submission of a trial transcript in an unrelated proceeding and relied on it to "make a finding of fact that controverted the plaintiff's own factual assertions set out in its complaint" (emphasis omitted)).

The Court declines to take judicial notice of the documents presented by Defendant because Plaintiff alleges that the pump at issue is different from what Defendant represents it to be, and Defendant has not shown that the Class II Control-IQ X2 Pump is the same model that Plaintiff alleges Decedent used. Defendant's motion references three models of its t:slim insulin pump: the Class II Control-IQ X2 Pump and "two previously approved . . . t:slim insulin pumps, both of which are Class III medical devices determined by the FDA to be safe and effective through the [PMA] process." (Def.'s Mem. 2.) Plaintiff alleges that Decedent used a t:slim insulin pump model that was approved through the PMA process. (*Id.*) Thus, because Plaintiff alleges that Decedent used a pump different from the Class II Control-IQ X2 Pump that Defendant argues Decedent used, there is a dispute as to the exact model t:slim insulin pump that Decedent used. The Court therefore declines to consider the documents Defendant proffers that

are suggestive of a different device than the one Plaintiff has pleaded.

c. Federal law preempts Plaintiff's claims

Defendant contends that Plaintiff's claims should be dismissed because they are both expressly and impliedly preempted. (Def.'s Mem. 1.) Defendant argues that Plaintiff's claims are expressly preempted because they "seek to impose state-law requirements that are different from the federal requirements," (*id*. at 1), and "challenge the design, labels, and warnings of the [X2] Pump . . . which were cleared by [the] FDA,"[4] (*id.* at 17–18). Defendant argues that Plaintiff's claims are impliedly preempted "insofar as they attempt to enforce the FDCA and FDA regulations" because "[o]nly the federal government may bring an action to enforce the FDCA or FDA regulations." (*Id.* at 18–19.)

Plaintiff argues that his claims fall within "exceptions to claims of express or implied preemption under the MDA" that courts have found "under circumstances similar to those here."

[4] Defendant contends that "[alt]hough [the device at issue is] Class II instead of Class III as Plaintiff alleges, the result [of the preemption analysis] is the same." (Def.'s Mem. 12.) The Court declines to decide whether Defendant is correct but notes that some of Defendant's arguments still apply even though the Court classifies the X2 Pump as a Class III device. The Court considers these arguments in deciding the motion. However, the Court declines to consider any of Defendant's arguments predicated on the X2 Pump being classified as a Class II device with special controls. For example, Defendant argues that any claim derived from Plaintiff's allegation that the X2 Pump should have "been designed or manufactured with 'thicker' materials" is preempted because FDA's special controls for the Class II device "require[] mechanical engineering testing." (*Id.* at 18; Def.'s Reply 6.) In addition, the two cases that Defendant relies on to demonstrate that other courts have dismissed cases "on grounds nearly identical to those argued" in this case, *Dickson v. Dexcom Inc.*, No. 24-CV-121, 2024 WL 4291511 (W.D. La. Sept. 25, 2024), and *Higginbottom v. Dexcom, Inc.*, 744 F. Supp. 3d 1058, 1082 (S.D. Cal. 2024), addressed Class II devices, (Def.'s First Notice 1; Def.'s Second Notice 1–2). *See Dickson*, 2024 WL 4291511, at *1, *3 (stating that the CGM device at issue "enter[ed] the market as a Class II medical device" and "was not subject to the more rigorous PMA for Class III devices"); *Higginbottom*, 744 F. Supp. 3d at 1082 (concluding based on complaint "allegations and the reasonable inferences therefrom" that "the t:slim pump [the decedent] was using at the time he died was a Class II device" and the court "cannot find that the device at issue is a Class III device having received PMA").

(Pl.'s Opp'n 11.) Plaintiff alleges that his "causes of action are all based on deviations from requirements in the FDA pre-approval process and/or violations of [f]ederal statutes and regulations." (Am. Compl. ¶ 37.)

Section 360k of the MDA preempts any state law that imposes a requirement on a medical device that is "different from, or in addition to, any requirement" under the FDCA and "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a); *Glover*, 6 F.4th at 233 (quoting § 360k(a)). The Supreme Court has established a two-step analysis for assessing whether the MDA expressly preempts a state law. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). First, the court "must determine whether the Federal Government has established requirements applicable to [the device at issue]." *Id.* at 321. "If so, [the court] must then determine whether the [plaintiff's] . . . claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness.'" *Id.* at 321–22 (quoting 21 U.S.C. § 360k(a)); *Koublani*, 2021 WL 2577068, at *5 (quoting same). The Supreme Court also concluded that section 360k preempts state common law claims "assert[ing] that the device in question 'violated state tort law notwithstanding compliance with the relevant federal requirements'" because such claims "impose[] requirements in addition to those imposed by federal law," *Glover*, 6 F.4th at 237 (quoting *Riegel*, 552 U.S. at 330), but noted that section 360k "does not prevent a [s]tate from providing a damages remedy for claims premised on a violation of FDA regulations" when "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Lohr*, 518 U.S. at 495); *see Glover*, 6 F.4th at 237 (quoting same); *Olmstead v. Bayer Corp.*, No. 17-CV-387, 2017 WL 3498696, at *3 (N.D.N.Y. Aug. 15, 2017) ("[C]ommon law claims challenging the safety of an FDA-approved medical device may survive preemption

only if they are 'premised on a violation of FDA regulations' where state law provides a damages remedy for such violations." (quoting *Riegel*, 552 U.S. at 330)). Such a "damages remedy does not amount to the additional or different 'requirement'" because "it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Lohr*, 518 U.S. at 495; *see Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 434 (2d Cir. 2015) ("[A] state law claim must be 'identical' to an existing federal requirement for such a claim to survive § 360k preemption." (quoting *Lohr*, 518 U.S. at 495)); *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 252 (E.D.N.Y. 2014) ("To avoid imposing state requirements on a device manufacturer which are in addition to or different from federal requirements, a plaintiff must establish that the state and federal requirements are equivalent.").

State laws not expressly preempted by the MDA may nevertheless be impliedly preempted under section 337(a) of the FDCA, which provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.'" *Glover*, 6 F.4th at 237 (alterations in original) (quoting 21 U.S.C. § 337(a)). Section 337(a) forecloses private rights of action under the FDCA against device manufacturers "for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions . . . ." (citing 21 U.S.C. § 337(a))); *Jackson-Mau v. Walgreen Co.*, 115 F.4th 121, 128 (2d Cir. 2024) (stating that "the FDCA provides no private right of action" (citing 21 U.S.C. § 337(a))). The Supreme Court has explained that "[t]o avoid implied preemption . . . claims must be based not on the FDCA, but on 'traditional state tort law which . . . predated the federal enactments in question[],'" *Glover*, 6 F.4th at 237 (alterations in

original) (quoting *Buckman*, 531 U.S. at 352–53), because "assigning liability *solely* on the basis of" a "newly-fashioned state cause of action . . . impose[s] significant and distinctive burdens on the FDA and the entities it regulates," *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. 2006) (discussing *Buckman*), *aff'd sub nom. Warner-Lambert Co, LLC. v. Kent*, 552 U.S. 440 (2008), and "would exert an extraneous pull on the scheme established by Congress," *Buckman*, 531 U.S. at 353.

In *Buckman*, the plaintiffs alleged that a consulting company for a bone screw manufacturer made fraudulent representations to the FDA when obtaining marketing approval and sought damages under state tort law. *Id.* at 343. The Supreme Court first explained that "[p]olicing fraud against federal agencies is hardly 'a field which the [s]tates have traditionally occupied,'" *id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)), and "the FDA has the sole authority 'to police fraud consistently with the Administration's judgment and objectives,'" *Glover*, 6 F.4th at 237 (quoting *Buckman*, 531 U.S. at 350). The Supreme Court "held that the *Buckman* plaintiffs' claims that the manufacturer had misled the FDA during the approval process were preempted because those 'fraud-on-the-FDA' claims 'exist[ed] solely by virtue of the FDCA disclosure requirements'" and noted that "permitting such claims to proceed would 'skew[ ] . . . [the] delicate balance of statutory objectives' the FDA seeks to achieve in enforcing the FDCA's requirements." *Id.* (quoting *Buckman*, 531 U.S. at 352–53). "To avoid implied preemption, the [Supreme] Court explained, claims must be based not on the FDCA, but on 'traditional state tort law which . . . predated the federal enactments in question[].'" *Id.* (quoting *Buckman*, 531 U.S. at 352–53) (alterations in original). "In *Buckman*, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements. And *Buckman* explicitly distinguished [an

earlier Supreme Court case addressing preemption, *Lohr*,] on this ground." *Desiano*, 467 F.3d at 95. "[*Lohr*], the *Buckman* Court said, involved a 'common-law negligence action against the manufacturer of an allegedly defective' product" that had not been approved through the PMA process." *Id.* (quoting *Buckman*, 531 U.S. at 352–53). "[T]he [*Lohr*] claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not *solely* from the violation of FDCA requirements." *Id*. (quoting *Buckman*, 531 U.S. at 352–53). "In [*Buckman*], however, the fraud claims exist[ed] *solely* by virtue of the FDCA disclosure requirements." *Id.* "Thus, although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that *any* violation of the FDCA will support a state-law claim." *Id.*

For a parallel claim to avoid implied preemption, "the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law — and that would give rise to liability under state law even if the FDCA had never been enacted." *Lafountain v. Smith & Nephew, Inc.*, No. 14-CV-1598, 2016 WL 3919796, at *4 (D. Conn. July 18, 2016) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). "Together, express and implied preemption under the FDCA, 'operating in tandem, have created what some federal courts have described as a "narrow gap" for pleadings.'" *Glover*, 6 F.4th at 237 (quoting *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017)). To fall into this narrow gap, a plaintiff must be suing for a device manufacturer's violation of an FDA requirement to avoid express preemption by MDA section 360k(a), but the plaintiff must not be suing because the device manufacturer violated the FDA requirement to avoid implied preemption under FDCA section 337(a). *Id.* at 237 ("The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must

not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." (quoting *In re Medtronic, Inc*., 623 F.3d 1200, 1204 (8th Cir. 2010))). "Putting these ideas into practice, . . . a plaintiff may proceed on her claim so long as she claims the 'breach of a well-recognized duty owed to her under state law' and so 'long as she can show that she was harmed by a violation of applicable federal law.'" *Mink*, 860 F.3d at 1327 (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)); *see Tillet v. CooperSurgical, Inc.*, No. 23-CV-6031, 2023 WL 4704091, at *2 (W.D.N.Y. July 24, 2023) ("In other words, in order to avoid express or implied preemption, the plaintiff's state law claim must 'parallel a federal-law duty under the MDA but also exist independently of the MDA.'" (quoting *A.F. By & Through Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018))); *Kaemmlein v. Abbott Lab'ys*, 564 F. Supp. 3d 58, 69 (E.D.N.Y. 2021) ("Plaintiff's state law claims fit within the 'narrow gap' between express preemption and implied preemption because she sufficiently claims 'the breach of a well-recognized duty owed to her under state law and . . . can show that she was harmed by a violation of applicable federal law[.]'" (quoting *Lewis v. Abbott Lab'ys*, No. 19-CV-909, 2020 WL 8254280, at *4 (M.D. Fla. Feb. 24, 2020)); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) ("For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA."); *see also Dunn v. Ancient Brands, LLC*, No. 21-CV-390, 2024 WL 2747646, at *2 (N.D.N.Y. May 29, 2024) ("[I]f the violation of an FDCA regulation is 'a critical element' of a plaintiff's cause of action but lacks a cause of action from a traditional state tort law predating the FDCA, then their lawsuit is duplicative of FDCA regulations and therefore impliedly preempted by those regulations." (quoting *Buckman*, 531 U.S. at 353)).

There is no controlling authority prescribing the detail required to plead a parallel claim that avoids preemption, but district courts within the Second Circuit have required that plaintiffs cite to a federal requirement specific to the device at issue that was violated and allege facts sufficient to link the violation to the alleged injury. *See Crissi v. Johnson & Johnson Vision Care, Inc.*, No. 15-CV-4230, 2016 WL 4502038, at *2 (E.D.N.Y. Aug. 25, 2016) ("[T]o survive preemption, claims must set forth a specific problem with or violation of federal law, be specific to the subject device and link that violation to the alleged injury."); *Burkett v. Smith & Nephew Gmbh*, No. 12-CV-4895, 2014 WL 1315315, at *4 (E.D.N.Y. Mar. 31, 2014) (finding that "none of [plaintiff's] claims state[d] a parallel claim because each fail[ed] (1) to allege a violation of federal law that is specific to the device at issue . . . and/or (2) to tie the alleged violation to [plaintiff's] purported injuries"); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 249 (S.D.N.Y. 2013) ("[T]o state a parallel claim plaintiff must 'set forth facts pointing to specific [premarket approval] requirements that have been violated,' and link those violations to his injuries." (second alteration in original) (first quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011); and then citing *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 204 (W.D.N.Y. 2011))); *see also Tansey v. Cochlear Ltd.*, No. 13-CV-4628, 2014 WL 4829453, at *9 (E.D.N.Y. Sept. 26, 2014) (quoting *Gale*).

Because FDA approved the X2 Pump at issue through the PMA process, the MDA preempts any state laws that impose on the X2 Pump safety and effectiveness requirements that are different from or in addition to the PMA requirements. *Desch v. Merz N.A., Inc.*, No. 22-CV-2688, 2023 WL 2734671, at *3 (E.D.N.Y. Mar. 31, 2023) ("Class III devices that receive the heightened review required for premarket approval are eligible for express preemption."); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 177 (N.D.N.Y. 2014) ("Medical devices that have

received pre-market approval automatically satisfy the first prong."); *Riegel*, 552 U.S. at 322–23 ("Premarket approval, in contrast, imposes 'requirements' under the MDA as we interpreted it" that are "specific to individual devices.").

As explained below, the Court finds that Plaintiff's claims for strict products liability based on manufacturing defect, negligent defective design, negligence, strict products liability based on failure to warn, and breach of implied warranty of merchantability are expressly preempted under MDA § 360(k).[5] Because Plaintiff has failed to state a cognizable federal violation for his claims, the Court declines to address whether Plaintiff's claims are impliedly preempted under FDCA § 337(a).

i. Strict products liability claim based on manufacturing defect

Defendant argues that Plaintiff's strict products liability claim based on manufacturing defect is preempted "because [it] seek[s] to challenge the design, labels, and warnings of the [X2 Pump] — all of which were cleared by FDA," (Def.'s Mem. 17–18), and Plaintiff has "not identified any specific FDA manufacturing requirements that [Defendant] failed to meet," (Def.'s Reply 4). Defendant contends that the "two voluntary international standards" that Plaintiff alleges the X2 Pump did not comply with, [International Electrotechnical Commission (IEC)]-60601 section 15.3.4 and 15.3.5, (Am. Compl. ¶ 34), "are not *FDA-imposed* manufacturing requirements, nor does Plaintiff allege they are in the Amended Complaint," (Def.'s Reply 4–5). In addition, Defendant argues that the alleged violations of the three sections

[5] Plaintiff alleges in the Amended Complaint that his "causes of action are also based on the express and implied warranties which were relied upon by [Decedent] prior to buying and using the device," (*id.* at ¶ 37), and that "Defendant is liable to Plaintiff for the negligent manufacturing defect," (*id.* ¶ 60), but does not allege any specific facts in support of such express warranty or negligent manufacturing defect claims in the Amended Complaint or offer any supporting arguments in his opposition to Defendant's motion. Therefore, Plaintiff has not pleaded nor does the Court consider an express warranty or negligent manufacturing defect claim.

of the Code of Federal Regulations ("C.F.R."), 21 C.F.R. §§ 820.30(c), 820.l00, and 820.186, (Am. Compl. ¶ 34), do not "contain specific manufacturing requirements," and Plaintiff does not allege "how [the sections] relate to the manufacturing of the [X2 Pump]," or "how the [X2 Pump] violated them," (Def.'s Reply 4 (emphasis omitted)). Defendant also argues that Plaintiff fails to "explain[] how [Defendant's] manufacturing process was in violation of federal requirements." (*Id.* at 5.)

Plaintiff argues that his claim is not preempted because he "has alleged that Defendant has deviated from the FDA manufacturing standards," "potential flaws" of the device "including mechanical malfunctions and design defects" that "if proven, may show . . . that the Defendant[] deviated from the FDA manufacturing standards," and that "the irregularities" of the device resulted in a manufacturing defect that caused Decedent's injury.[6] (Pl.'s Opp'n 13–15.)

"Under New York's modern approach to products liability, a product has a defect that renders the manufacturer liable for the resulting injuries if it: (1) contains a manufacturing flaw; (2) is defectively designed; or (3) is not accompanied by adequate warnings for the use of the product." *In re N.Y.C. Asbestos Litig.*, 27 N.Y.3d 765, 787 (2016) (internal quotation marks omitted) (collecting cases). "[T]here are four theories under which a plaintiff may pursue a

[6] Plaintiff also argues that traditional tort claims involving Class III devices are not preempted, (Pl.'s Opp'n 11–13), but misstates the law. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) ("[E]xcluding common-law duties from the scope of pre-emption would make little sense."). As discussed above in Section I.c, the Supreme Court cases addressing MDA preemption have created a "narrow gap" through which state law tort claims may survive preemption, *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 237 (2d Cir. 2021), and it is only those "tort claims that are based on a manufacturer's departure from the standards set forth in the device's approved PMA application" that "are not preempted." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2d Cir. 2006), *aff'd*, 552 U.S. 312. The two New York state court cases on which Plaintiff relies, *Heymach v. Cardiac Pacemakers, Inc.*, 698 N.Y.S.2d 837 (N.Y. Sup. Ct. 1999), and *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16 (N.Y. App. Div. 1997), predate the Supreme Court's clarification of the scope of MDA preemption in *Riegel*.

recovery based upon a claim of products liability: (1) strict liability; (2) negligence; (3) express warranty; and (4) implied warranty." *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 888 (E.D.N.Y. 2018) (first citing *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 252 (E.D.N.Y. 2014); and then citing *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 106–07 (1983)). To prevail on a manufacturing defect claim under theories of strict liability, negligence, or breach of express or implied warranty, a plaintiff must allege that the specific product that caused the plaintiff's injury was not manufactured as designed or was not built to specifications. *See Tears v. Bos. Sci. Corp.*, 344 F. Supp. 3d 500, 510–11 (S.D.N.Y. 2018); *see also Minda v. Biomet, Inc.*, No. 98-9533, 1999 WL 491877, at *1 (2d Cir. July 7, 1999) ("To prove the existence of a manufacturing defect, a plaintiff must establish that the product was not built to specifications or that it did not conform to the manufacturer's intended design."); *McCarthy v. Olin Corp.*, 119 F.3d 148, 154–55 (2d Cir. 1997) (finding that "a manufacturing defect . . . results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm").

Plaintiff has failed to sufficiently plead an FDA requirement specific to the X2 Pump that Defendant violated in manufacturing the device. Although Plaintiff generally alleges that the manufacturing defect claims, like his other "causes of action," derive from Defendant's alleged "deviations from requirements in the FDA pre-approval process," (Am. Compl. ¶ 37), Plaintiff does not specify the manufacturing requirements from the PMA process that Defendant failed to meet. *See Desabio*, 817 F. Supp. 2d at 204–05 ("To properly allege parallel claims, the complaint must set forth facts[] pointing to specific PMA requirements that have been violated." (quoting *Wolicki-Gables*, 634 F.3d at 1301)). Even accepting Plaintiff's allegation that Defendant violated "[IEC] technical standards for the safety and essential performance of

medical electrical equipment," (Pl.'s Opp'n 15; Am. Compl. ¶ 34), as pleaded, this factual allegation is irrelevant to the question of whether Defendant violated "device-specific federal requirements," *Riegel*, 451 F.3d at 116, because there are no allegations that FDA imposed the IEC standards on the X2 Pump through the PMA process or otherwise. Similarly, Plaintiff's vague allegations that Defendant violated "accepted standards for medical device risk management," (Am. Compl. ¶ 34), are insufficient to meet the pleading requirement because Plaintiff does not specify what the "accepted standards" are nor that the FDA imposed them on Defendant during the PMA process.

Moreover, even assuming that Defendant failed to "establish and maintain procedures to ensure that the design requirements relating to [the X2 Pump] are appropriate" under 21 C.F.R. § 820.30(c); "establish and maintain procedures for implementing corrective and preventive action," under 21 C.F.R. § 820.100; and "maintain a quality system record," under 21 C.F.R. § 820.186, and further assuming that these C.F.R. provisions did constitute device-specific requirements, Plaintiff's parallel claim still fails because he has not explained how the requirements apply to the X2 Pump nor how Defendant violated them in manufacturing Decedent's X2 Pump. *See Dains v. Bayer HealthCare LLC*, No. 22-CV-208, 2022 WL 16572021, at *8 (N.D.N.Y. Nov. 1, 2022) (holding that manufacturing defect claims against female contraception device manufacturer were preempted because plaintiff did not "plausibly allege that the specific [device at issue] . . . was manufactured in a way that violated FDA-approved specifications"); *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550, 559 (N.D.N.Y. 2020) (concluding that plaintiff's manufacturing defect claim against breast implant manufacturers was preempted because plaintiff failed to specifically allege "how [the d]efendants' manufacturing process was in violation of federal requirements"); *Olmstead*, 2017

WL 3498696, at *1, *4 (concluding that the plaintiff's manufacturing defect claim against female contraception device manufacturer was preempted partly because the plaintiff failed to explain how defendants violated the alleged FDA regulations). Part 820 of Title 21 of the CFR encompasses FDA's Current Good Manufacturing Practices (CGMP), "which establish general requirements for most steps in every device's manufacture." *Lohr*, 518 U.S. at 483; 21 C.F.R. § 820.1(a)(1).

Courts are divided as to whether an alleged violation of the generally applicable requirements of CGMPs is alone a sufficient basis for a parallel claim to survive preemption.[7] *See Ortiz v. Allergan, Inc.*, No. 14-CV-8188, 2015 WL 5178402, at *3 n.4 (S.D.N.Y. Sept. 4, 2015) ("Courts 'have disagreed as to whether a plaintiff can plead a parallel claim' by alleging that a defendant violated the CGMPs, which are general regulations that apply to all medical

[7] Some courts have found that a showing that a manufacturer violated a CGMP is sufficient to state a parallel claim. *See Simoneau v. Stryker Corp.*, No. 13-CV-1200, 2014 WL 1289426, at *7 (D. Conn. Mar. 31, 2014) (concluding that "[the plaintiff's] reliance on generally applicable CGMPs [was] permissible" and sufficient "to state a parallel [state law] claim based on strict liability for a manufacturing defect alleged to have personally injured her"); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 158–60 (S.D.N.Y. 2011) (concluding that "a defective manufacturing claim based upon a violation of [21 C.F.R. § 808(1)(d)] is not preempted"). Other courts have found that violations of CGMPs alone cannot sustain a valid parallel claim. *See Moody v. Allergan USA, Inc.*, No. 16-CV-901, 2017 WL 6949742, at *4 n.1 (W.D.N.Y. Dec. 5, 2017) (noting "that alleged violations of CGMPs, standing alone, are insufficient to sustain a parallel claim"), *report and recommendation adopted*, 2018 WL 451824 (W.D.N.Y. Jan. 17, 2018); *Olmstead v. Bayer Corp.*, No. 17-CV-387, 2017 WL 3498696, at *4 (N.D.N.Y. Aug. 15, 2017) (concluding that "allowing a suit to continue on the basis of the CGMPs would necessarily impose standards that are different from, or in addition to those imposed by the MDA — precisely the result that the MDA preemption provision seeks to prevent" (internal quotation marks omitted)); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (holding that where "a plaintiff relies on nothing more tha[n CGMPs] in support of a parallel cause of action, preemption bars the claim"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) ("Plaintiff's 'reliance on [defendants' violations of] CGMPs and [quality system regulations] . . . does not save these claims from preemption . . . [as such requirements] are simply too generic, standing alone, to serve as the basis for [her] manufacturing-defect claim[].'" (alterations in original) (citation omitted)).

devices, or whether plaintiffs must allege a violation of a device-specific regulation." (citation omitted)). *Cf. Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 218–20 (E.D.N.Y. 2017) (explaining the "split of authority" in the Second Circuit before concluding that "[t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs, but rather the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury" (quoting *Bass v. Stryker Corp.*, 669 F.3d 501, 511–12 (5th Cir. 2012)). Most courts addressing the issue in the Eastern District of New York have concluded that CGMPs do not form a sufficient basis for a parallel claim,[8] and courts that have allowed such claims to proceed have done so only when the alleged CGMP violation also gives rise to a violation of PMA requirements.[9]

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[8] *See, e.g.*, *Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 218–20 (E.D.N.Y. 2017) (device manufacturer's alleged CGMP violations did not support a parallel claim because the "vague and open-ended" CGMPs "do not impose specific duties" and "state-law claims premised on a violation of" them may create "varying standards that would be 'different from, or in addition to' those required by the federal scheme" (citations omitted)); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 197–98 (E.D.N.Y. 2015) (device manufacturer's alleged violation of the CGMPs' "minimum standards" cannot substantiate a parallel claim because "CGMPs are guidelines that do not create a federal requirement, . . . a claim based on alleged failure to comply with the guidelines fails to plead violation of a federal requirement[,]" and [t]o permit a claim that mandates compliance with such 'vague' standards effectively imposes 'different, or additional' requirements" (citations omitted)); *Burkett v. Smith & Nephew Gmbh*, No. 12-CV-4895, 2014 WL 1315315, at *5 (E.D.N.Y. Mar. 31, 2014) ("Because [plaintiff's] manufacturing defect claim is based on violation of generally applicable CGMPs, as opposed to federal requirements specific to the [medical device at issue], preemption bars the claim.").

[9] *See, e.g.*, *Tansey v. Cochlear Ltd.*, No. 13-CV-4628, 2014 WL 4829453, at *10 (E.D.N.Y. Sept. 26, 2014) (quoting *Franzese v. St. Jude Med., Inc.*, No. 13-CV-3203, 2014 WL 2863087, at *5 (E.D.N.Y. June 23, 2014), and concluding that plaintiff's allegations that a device manufacturer violated CGMPs regarding production and process controls, 21 C.F.R. § 820.70(a),(h), gave rise to federal violations sufficient to state a parallel claim because the "complaint allege[d] that [the manufacturer] deviated from the FDA approved plan and specifications and that the deviation . . . was the cause of plaintiff's injury"); *Franzese*, 2014 WL 2863087, at *4–5 (concluding that the allegation that a device manufacturer's "unsanctioned

Even if the Court were to assume without deciding that CGMPs may substantiate a parallel claim, Plaintiff does not allege that the FDA imposed the CGMPs on the X2 Pump through the PMA process nor that Defendant failed to (1) "establish and maintain procedures to ensure that the design requirements relating to [the X2 Pump] are appropriate," as required by 21 C.F.R. § 820.30(c); (2) "establish and maintain procedures for implementing corrective and preventive action," as required by 21 C.F.R. § 820.100; or (3) "maintain a quality system record," as required by C.F.R. § 820.186. *See Tansey*, 2014 WL 4829453, at *9 ("To avoid preemption and satisfy the *Twombly* and *Iqbal* pleading standards, plaintiffs suing with regard to a PMA-approved device cannot simply make the conclusory allegation that defendant's conduct violated FDA regulations." (quoting *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013))).

In addition, Plaintiff's allegation that "the pump was operating outside of specifications," (Am. Compl. ¶ 30), fails to state the specifications that the X2 Pump did not comply with or whether the specifications govern design or manufacturing. *See Tillet*, 2023 WL 4704091, at *3 ("Plaintiff's vague and generic assertions are insufficient to plausibly allege a manufacturing defect because they do not identify or otherwise explain the specific 'conditions' that allegedly deviated from the approved product design."). In addition, although Plaintiff alleges that the X2 Pump could have been "manufactured with thicker, more stable materials, so as to adequately hedge for the possibility that the pump would be dropped or other errors would be prevented," (Am. Compl. ¶ 32), there are no allegations that the thickness of the materials deviated from the FDA-approved design. *See Norman v. Bayer Corp.*, No. 16-CV-253, 2016 WL 4007547, at *3 (D. Conn. July 26, 2016) ("[T]o avoid preemption on a manufacturing defect claim, plaintiff

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adulterations" due in part to a failure to comply with CGMP process validations requirements could state a parallel claim "where the violation of CGMPs also indicate a deviation from PMA requirements").

must allege that her device was not manufactured in conformance with the specifications approved by the FDA."). Thus, Plaintiff has not linked any alleged deficiencies in the manufacturing process to defects in Decedent's device or her injuries and death.

Plaintiff's arguments that his claims are not preempted because he has pointed to "potential flaws" that "may show that the device failed to comply with design specifications and that the Defendant[] deviated from the FDA manufacturing standards," (Pl.'s Opp'n 13), as well as showed that these irregularities caused the manufacturing defect, (*id.* at 14), are insufficient to plead a parallel claim.[10] Even accepting as true that "the cartridge was not loading into the [X2 Pump] in [Decedent's] possession on January 21, 2022, due to mechanical malfunctions of and design defects with the" X2 Pump, including an out-of-alignment drive mechanism, drive train failure, noncompliance with FDA design failure modes as to droppage; and inadequate and improper "design[] to withstand being dropped," (Am. Compl. ¶ 17), to plead a parallel claim and survive preemption, Plaintiff must allege facts to support the allegations that Defendant violated device-specific manufacturing requirements. A mere listing of "mechanical malfunctions" or purported "design flaws" are not substitutes. *See Sheinfeld v. B. Braun Med. Inc.*, No. 23-CV-1622, 2024 WL 635483, at *3 (S.D.N.Y. Feb. 1, 2024), (rejecting "[p]laintiff's circular arguments that . . . . because the [Class III medical device at issue] migrated after

[10] In support of his argument that his claims are not preempted because he has alleged "potential flaws" that "may show that the device failed to comply with design specifications and that the Defendant[] deviated from the FDA manufacturing standards," and showed that these irregularities caused the manufacturing defect, (Pl.'s Opp'n 13–14), Plaintiff relies on *Ortiz v. Bayer Corp.*, No. 20-CV-4266, 2022 WL 17817726 (E.D.N.Y. Dec. 13, 2022), a report and recommendation (R&R) that was never adopted as to the manufacturing defect claim. *See Ortiz*, No. 20-CV-4266 (E.D.N.Y. Mar. 31, 2023) (order finding no clear error as to R&R for failure to train claim only and adopting in part R&R); *Ortiz*, No. 20-CV-4266 (E.D.N.Y. June 8, 2023) (order granting leave to amend pleading and denying in part motion to dismiss for failure to state a claim as to manufacturing defect claim without adopting or reviewing the R&R for clear error).

surgery, there must have been negligence in its manufacture or design" and dismissing the claims in the absence of allegations that the device "violate[d] any specific federal requirement that could be the basis for a parallel state claim"), *report and recommendation adopted sub nom.* 2024 WL 1075329 (S.D.N.Y. Mar. 12, 2024).

Plaintiff appears to argue that the Court should infer that because the X2 Pump had "flaws," Defendant did not comply with FDA design specifications or manufacturing requirements. (Pl.'s Opp'n 13.) *See Sacerdote*, 9 F.4th at 106–07 ("[A court] must . . . draw[] all reasonable inferences in the plaintiff['s] favor."). As the Supreme Court recognized in *Riegel*, the FDA grants PMA based on a "reasonable assurance of the device's safety and effectiveness" and "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318 (internal quotation marks omitted); *see Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 496 (W.D. Pa. 2012) ("[T]he PMA process does not certify the absolute safety of medical devices; rather, the process entails the balancing of risks and benefits by the FDA throughout the approval process." (citing *Riegel*, 552 U.S. at 318)). Thus, a Class III medical device cleared through a PMA process could theoretically fail to perform as intended or harm the end user notwithstanding the device manufacturer's compliance with device-specific federal requirements. *See Banner v. Cyberonics, Inc.*, No. 08-CV-0741, 2010 WL 455286, at *4 (D.N.J. Feb. 4, 2010) ("[I]f the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a device thereby produced that nevertheless does not function as intended does not give rise to liability."). Plaintiff must plead a device-specific FDA requirement and facts sufficient to support that Defendant violated the requirement to state a parallel claim.

Because Plaintiff has failed to plead a manufacturing defect claim that parallels rather

than adds to the FDA requirements imposed by the PMA, the Court finds that Plaintiff's strict products liability claim based on manufacturing defect is preempted.

ii. Negligent defective design claim

Defendant argues that Plaintiff's negligent defective design claim is preempted "because [it] seek[s] to challenge the" X2 Pump's design, which the FDA cleared. (Def.'s Mem. 17–18.) In support, Defendant argues that Plaintiff's allegations that "the Pump should have been designed to 'withstand being dropped,'" (*see* Am. Compl ¶¶ 18, 30–32), are preempted because "Plaintiff has not alleged how the [X2 Pump's] design or manufacture violated any federal requirements applicable to it," (Def.'s Mem. 12), and accepting Plaintiff's arguments would "impose safety-related requirements on the [X2 Pump] beyond those imposed by the FDA" (Def.'s Reply 6). Defendant also argues that "[t]o the extent Plaintiff is arguing separate causes for drive train force/alignment or cartridge load issues other than inadequate drop resistance, Plaintiff has not alleged sufficient detail to state a claim" nor has Plaintiff "stated how any claims based [on] those issues are premised on the violation of FDA regulation, or that Plaintiff's state law claims exist independently of such FDA regulations." (Def.'s Mem. 18 n.36.)

Plaintiff advances similar arguments to the ones he makes against preemption of his strict liability manufacturing claim, such as that he has alleged "potential flaws" of the device "including mechanical malfunctions and design defects" that "if proven, may show that the device failed to comply with design specifications and that the Defendant deviated from the FDA manufacturing standards." (Pl.'s Opp'n 13–15.)

"Under New York law . . . a plaintiff can assert claims for injury due to an allegedly defective product under theories of negligence [and other theories]."[11] *Delgado v. Universal*

[11] "New York courts generally consider strict products liability and negligence claims to

Beauty Prods., Inc., No. 22-2727, 2024 WL 1298509, at *1 (2d Cir. Mar. 27, 2024) (summary order). "In New York, to establish a design defect, a plaintiff must 'present evidence that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner.'" *In re Sears Holdings Corp.*, No. 21-1095, 2023 WL 3938982, at *1 (2d Cir. June 12, 2023) (quoting *Voss*, 59 N.Y.2d at 108); *Michael v. Gen. Motors LLC*, 790 F. App'x 275, 277 n.1 (2d Cir. 2019) (same). In addition, "to establish a prima facie case, the plaintiff is required to show that the defectively designed product caused his injury and that the defect was the proximate cause of the injury." *In re Sears*, 2023 WL 3938982, at *1 (first quoting *Voss*, 59 N.Y.2d at 109; and then citing *Doomes v. Best Transit Corp.*, 17 N.Y.3d 594, 608 (2011)). The plaintiff bears the burden of showing "that a defect in the product was a substantial factor in causing the injury." *Kosmynka v. Polaris Indus., Inc.*, 462 F.3d 74, 86 (2d Cir. 2006) (emphasis omitted) (quoting *Fritz v. White Consol. Indus., Inc.*, 762 N.Y.S.2d 711, 714 (App. Div. 2003)). "[T]he relevant inquiry is whether the product as designed was not reasonably safe — that is, whether it is a product which, if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner." *DiBartlo v. Abbot Lab'ys*, 914 F. Supp. 2d 601, 621 (S.D.N.Y. 2012) (citation and internal quotation marks omitted).

Plaintiff's negligent design defect claim falls squarely within the MDA's express preemption provision because Plaintiff fails to allege that the design defects were due to deviations from PMA requirements. Plaintiff's vague and conclusory allegations that

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be functionally synonymous." *S.F. v. Archer Daniels Midland Co.*, 594 F. App'x 11, 12 (2d Cir. 2014) (citations omitted). *But see Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716, 720 (S.D.N.Y. 2017) ("Design defect strict products liability claims differ from negligently designed product claims 'in that the plaintiff is not required to prove that the manufacturer acted unreasonably in designing the product.'" (citations omitted)).

Defendant violated IEC standards, three provisions of FDA's CGMPs, and accepted standards for medical device risk management, (Pl.'s Opp'n 14), are insufficient to allege that Defendant deviated from the FDA's approved design for the same reasons they do not substantiate a parallel claim that survives preemption for the alleged manufacturing defects. Plaintiff's allegations that "the [X2 Pump] could have been designed in such a way as to decrease the likelihood of mechanical failure or failure as a result of the pump being dropped, such as by using thicker or sturdier materials so as to make the pump less fragile; by more fully appreciating the likelihood that an insulin pump designed for everyday use would be dropped . . . and by not sacrificing durability for style in designing the pump and weighing the trade-off of a bigger, heavier, and more durable pump versus one that is slimmer and presumably more portable," (*id.* at ¶ 18), as pleaded, directly challenge the FDA-approved design for the X2 Pump and thus would impose design requirements that are "different from, or in addition to" that which FDA approved through the PMA process. *Riegel*, 552 U.S. at 316 (quoting § 360k(a)); *see Cordova v. Smith & Nephew, Inc.*, No. 14-CV-351, 2014 WL 3749421, at *6 (E.D.N.Y. July 30, 2014) ("Because [plaintiff] does not claim that the design of the [device at issue] differed from the design approved by the FDA, [plaintiff's] design defect claim boils down to a direct attack on the very design approved by the FDA.").

Construing the Amended Complaint liberally, Plaintiff almost pleads a negligent design defect claim based on the X2 Pump's failure to "comply with FDA design failure modes as to droppage" that survives preemption,[12] (Am. Compl. ¶ 17), but fails to allege facts from which

[12] Plaintiff also alleges that the X2 Pump was "further subject to certain voluntary standards as part of the FDA process, including a drop test for infusion pumps," (Am. Compl. ¶ 14), but because Plaintiff states that this standard is voluntary, the Court does not consider the allegation as establishing a device-specific FDA requirement. However, to the extent that

the Court may infer that Defendant failed to comply with a PMA requirement that applied post-approval. Plaintiff alleges that Decedent's X2 Pump was defective in that the device could not withstand droppage, that the defect was due to Defendant deviating from FDA's approved design as related to failure modes that were "set by the FDA as part of the pre-approval process," (*Id.* ¶¶ 17–18), and that the defect caused the Decedent's injury in that the X2 Pump, which showed signs of being dropped, stopped delivering insulin to Decedent, resulting in her death.[13] *Cf. Burkett*, 2014 WL 1315315, at *4 (dismissing design defect claim as preempted because the complaint did not "allege that [the defendant] altered the design of the device from the design approved by the FDA" nor did it "link any purported violations of federal requirements to [plaintiff's] alleged injury"). For Plaintiff's claim to survive preemption, Plaintiff would need to sufficiently plead or allege facts from which the Court could infer that the requirements "set by the FDA as part of the pre-approval process" governed screenings for failure modes that Defendant was required to conduct after receiving PMA for the X2 Pump to ensure continued

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Plaintiff is alleging that Defendant' failed to comply with voluntary drop tests as part of the PMA process, the claim is preempted.

[13] Plaintiff alleges that "as part of the FDA pre-approval process," the X2 Pump is "required to comply with multiple failure modes, including in anticipation of the potential that the pump may be dropped." (Am. Compl. ¶ 13.) He contends that the X2 Pump "did not comply with FDA design failure modes as to droppage," (*id.* ¶ 17), that were "set by the FDA as part of the pre-approval process," (*id.* ¶ 18), as Defendant failed "to appropriately screen the device for certain failure modes, including droppage," (*id.* ¶ 66), and due, at least in part, to Defendant's noncompliance, the insulin cartridge in Decedent's X2 Pump was not loading on January 21, 2022, (*id.* ¶¶ 17–18, 54). "[A]s a result[, the X2 Pump] did not deliver the insulin that [Decedent] needed and relied upon as a diabetic," "causing serious injuries and damages to" Decedent, including "severe emotional distress and anxiety, symptoms associated with rapid blood glucose changes, [and] death." (*Id.* ¶¶ 50, 54–55.) Plaintiff also alleges that Decedent's report found evidence that the pump had been dropped, (*id.* ¶ 31), and that the "[X2 Pump] could have been designed in such a way as to decrease the likelihood of mechanical failure or failure as a result of the pump being dropped . . . by complying with failure modes set by the FDA as part of the pre-approval process," (*id.* ¶ 18).

compliance with the FDA-approved design specifications. Plaintiff fails to do either in the Amended Complaint. Plaintiff alleges that "Defendant's design . . . of the [X2 Pump] violated its obligations under relevant federal and state regulations governing the post-marke[t] conduct of Class III infusion pumps . . . ," (*id.* ¶ 33), but this allegation is insufficient because it does not refer to any specific federal requirements for post-approval design failure mode screenings that FDA imposed on the X2 Pump in the PMA documents.

In the absence of a basis from which to draw the inference of a post-PMA violation, Plaintiff's Amended Complaint supports that the design failure mode screening requirements "set by the FDA as part of the pre-approval process" were for Defendant to conduct screenings before FDA approved the final design. (*Id.* ¶ 18.) In particular, Plaintiff alleges that "the [X2 Pump] could have been designed in such a way as to decrease the likelihood of mechanical failure or failure as a result of the pump being dropped, such as by using thicker or sturdier materials so as to make the pump less fragile; by more fully appreciating the likelihood that an insulin pump designed for everyday use would be dropped; *by complying with failure modes set by the FDA as part of the pre-approval process*; and by not sacrificing durability for style in designing the pump and weighing the trade-off of a bigger, heavier, and more durable pump versus one that is slimmer and presumably more portable." (*Id.* ¶ 18 (emphasis added).) In context, Plaintiff's allegation that Defendant failed to comply with failure modes set by the FDA as part of the pre-approval process challenges the sufficiency of the failure mode testing that the FDA found to be adequate to approve the X2 Pump's design, a claim that is expressly preempted under section 360(k). *See, e.g.*, *Bertini*, 8 F. Supp. 3d at 254 ("[A]n action based on state law that would require a manufacturer to design a device, which has already received [premarket] approval, in a manner that is safer than what the FDA requires would impose additional state

safety requirements on the device, and therefore this claim would be preempted under § 360k."). Thus, even viewing the allegations in the light most favorable to Plaintiff, the Amended Complaint fails to "plausibly give rise to a claim that is not preempted." *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 444 (2d Cir. 2015) (explaining that "in the context of a motion to dismiss," the factual allegations relevant to a preemption argument "must be viewed in the light most favorable to the plaintiff" and a "district court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted" (citations omitted)).

Accordingly, the Court finds that Plaintiff's negligent design defect claim is preempted.

iii. Negligence, failure to warn, and breach of implied warranty of merchantability claims

Defendant argues that Plaintiff's negligence, failure to warn, and breach of implied warranty of merchantability claims are preempted "because they seek to challenge the design, labels, and warnings of the [X2 Pump] — all of which were cleared by FDA." (Def.'s Mem. 17–18.)

Plaintiff argues that the claims are "general common tort law claims under New York law" for which "no specific New York state or local requirements . . . are at odds with specific [f]ederal requirements under the MDA as concerning insulin pumps." (Pl.'s Opp'n 12.)

"Under New York law, a tort plaintiff seeking to prove a defendant's negligence must show: '(1) the existence of a duty on defendant's part as to plaintiff; (2) a breach of this duty; and (3) injury to the plaintiff as a result thereof.'" *Union Mut. Fire Ins. Co. v. Ace Caribbean Mkt.*, 64 F.4th 441, 445 (2d Cir. 2023) (quoting *Borley v. United States*, 22 F.4th 75, 78 (2d Cir. 2021)); *see also Coyle v. United States*, 954 F.3d 146, 148 (2d Cir. 2020) ("To establish liability [for a negligence claim] under New York law, a plaintiff must prove (1) that the defendant owed

her a duty; (2) that the defendant breached that duty; and (3) that she suffered injuries proximately resulting from that breach." (citing *Solomon ex rel. Solomon v. City of New York*, 66 N.Y.2d 1026, 1027 (1985))). To establish a claim for failure to warn, a plaintiff must prove "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App'x 8, 10 (2d Cir. 2011) (citing *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998)); *see also Buono v. Tyco Fire Prods., LP*, 78 F.4th 490, 497 (2d Cir. 2023) ("To succeed on their failure-to-warn claim, [the] plaintiffs were required to prove that the product did not contain adequate warnings and that the inadequacy of those warnings was the proximate cause of the injuries." (quoting *Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 285 (App. Div. 2007))). Under the New York law, the implied warranty of merchantability requires that the product sold be reasonably fit for the ordinary purpose for which it was intended. *See Rienzi & Sons, Inc. v. I Buonatavola Sini S.R.L.*, No. 20-CV-5704, 2024 WL 3965989, at *9 (E.D.N.Y. Aug. 27, 2024) (explaining that under New York law, "[t]he standard of merchantability requires that the goods be 'fit for the ordinary purposes for which such goods are used.'" (quoting N.Y. U.C.C.§ 2-314(2)(c))). Section 2–314 of the New York Uniform Commercial Code ("UCC") provides, in pertinent part, that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." N.Y. U.C.C. § 2–314(1). To be merchantable, the goods must be: (1) fit for the ordinary purpose for which they are used; (2) capable of passing without objection in the trade under the contract description; and (3) of fair and average quality for such goods. N.Y. U.C.C. § 2–314(2)(a)–(c).

Plaintiff's claims are preempted because Plaintiff fails to state an FDA violation that may

form the basis of a parallel claim. In support of his negligence claim, all the duties under New York law that Plaintiff alleges Defendant breached, and that are distinct from the duty alleged under his negligent defective design claim,[14] would necessarily impose requirements that are "different from, or in addition to" that which FDA approved through the PMA process because Plaintiff fails to allege any FDA-imposed duties that are equivalent to the purported New York law duties. *See Babayev*, 228 F. Supp. 3d at 217–19 (finding negligence claim against medical device manufacturer was preempted because plaintiff failed to "allege violations of device-specific premarket approval requirements" that "could give rise to a parallel claim"); *Nagel v. Smith & Nephew, Inc.*, No. 15-CV-927, 2016 WL 4098715, at *8 (D. Conn. July 28, 2016) (dismissing as preempted negligence claims alleging that medical device manufacturer "knew or should have known in the exercise of reasonable care that it should inspect, test, and monitor the [metal liner for a hip replacement device], and the process of manufacturing the metal liners, as required under the FDA's premarket approval monitoring and reporting requirements" because "[a]llowing a plaintiff to claim that a particular testing or manufacturing regime was negligently inadequate, despite being required or allowed by the FDA, would establish an additional requirement beyond federal law and is subject to express preemption under § 360k"); *Bertini*, 8 F. Supp. 3d at 258 (dismissing negligence claim as preempted because "in arguing that defendant

[14] Plaintiff alleges that Defendant had duties to "exercise reasonable care and to comply with existing standards of care in the preparation . . . development, formulation, manufacture, testing, packaging, promotion, labeling, advertising, marketing, instruction of use, warning about distribution, supply, and/or sale of the" X2 Pump, (Am. Compl. ¶ 42); "to ensure that those using the [X2 Pump], including [Decedent], would not suffer from unreasonable, dangerous, or adverse events or effects while using the product in their normal, intended, and/or foreseeable manner(s), (*id.* ¶ 43); "to ensure that those using the [X2 Pump], including [Decedent], would not significantly increase their risk of bodily harm and adverse events or effects," (*id.* ¶ 44); and "duty to advise [Decedent] to call 911 and a duty to itself call 911 or any further contacts upon not obtaining a return phone call from [Decedent], (*id*. ¶ 48).

was negligent for not noticing that its design was defective" plaintiff was "attempting to hold defendant liable for not designing the R3 metal liner in a manner safer than what the FDA requires" and "would impose additional safety requirements on defendant's device beyond what is required by federal regulations").

In support of his failure to warn claim, Plaintiff alleges that "Defendant failed to provide adequate safe-use instructions and/or adequate warnings to consumers despite Defendant's knowledge of the risks," (Am. Compl. ¶ 69), and "knew about but failed to inform their consumers, including [Decedent], of the risks of using the [X2 Pump]," (*id.* ¶ 70). Plaintiff fails to plead a parallel claim because he does not allege that Defendant failed to comply with the labeling or other warning requirements that the FDA imposed through the PMA process nor does he plead a state duty that would parallel any such violation by Defendant. *Cf. Glover v. Bausch & Lomb Inc.*, 43 F.4th 304, 307 (2d Cir. 2022) (holding that plaintiffs' state law negligence and failure-to-warn claims against a Class III device manufacturer survived preemption because the state's tort law "provides a cause of action based on a manufacturer's failure to report adverse events to a regulator like the FDA, or to comply with post-approval requirements set by that regulator" (quoting *Glover*, 6.4th at 239)).

Plaintiff's allegations that "Defendant breached the implied warranty of merchantability because the [X2] was defective," "would not pass without objection due to the malfunction(s)," "was not fit for normal use, and therefore failed to conform to the standard of like products in the trade," (Am. Compl. ¶ 77), are not sufficiently detailed for the Court to determine which alleged design or manufacturing defects Plaintiff is relying on as the basis of his breach of implied warranty of merchantability claim. Without clarity as to which alleged defects Plaintiff claims caused the X2 Pump as sold not to be reasonably fit for the purpose for which it was intended,

the Court cannot determine whether Plaintiff has identified an FDA violation for the underlying defects sufficient to state a parallel claim. Moreover, even if Plaintiff had specified the defects forming the basis for his claim, as discussed in Sections II.c.i-ii *supra*, Plaintiff has not sufficiently pleaded that any of the design or manufacturing defects alleged in the Amended Complaint were due to Defendant violating specific FDA requirements imposed on the X2 Pump. *See Bertini*, 8 F. Supp. 3d at 260 (concluding that breach of implied warranty claim against device manufacturer was preempted because plaintiff failed to "identify[] any FDA regulations that defendant . . . violated"). Because Plaintiff has not clearly alleged an FDA violation, he is claiming that the FDA-approved X2 Pump was not "reasonably fit," in direct conflict with FDA's determination that it had reasonable assurance of the product's safety and effectiveness as an insulin pump. *See Webb*, 453 F. Supp. 3d at 560 (holding that plaintiff's breach of implied warranty claim against breast implant manufacturers was preempted because plaintiff "failed to allege that the [manufacturers'] federal violations caused the [implants] to have deviated from their purpose, that they failed, or that they were unfit for patients").

Accordingly, the Court finds that Plaintiff's negligence, failure to warn, and implied warranty claims are preempted.

d. Plaintiff's wrongful death claim is dismissed for failure to state a claim

Defendant asserts that all of Plaintiff's claims are preempted for failure to "allege[] a viable parallel claim," (*see* Def.'s Reply 1–2), and should be dismissed because "Plaintiff failed to plead sufficient facts to support any theories of liability under New York State Law," (Defs.' Mem. 1), but does not provide specific arguments as to why the wrongful death claim should be dismissed.

Plaintiff argues that his wrongful death claim is a "general common tort law claim[]

under New York law" for which "no specific New York state or local requirements . . . are at odds with specific [f]ederal requirements under the MDA as concerning insulin pumps." (Pl.'s Opp'n 12.) Plaintiff also contends that he has pleaded "sufficient facts in the Amended Complaint to support [his] claims." (*Id.* at 23.)

In New York, wrongful death is an exclusively statutory cause of action. N.Y. Est. Powers & Trusts Law § 5-4.1; *Barbara v. United States*, No. 17-CV-1982, 2020 WL 5658724, at *6 (E.D.N.Y. Sept. 23, 2020) ("There is no common law wrongful death cause of action to recover damages in New York, rather, a party can only bring a statutory wrongful death action." (citations omitted)); *Hernandez v. N.Y.C. Health & Hosps. Corp.*, 78 N.Y.2d 687, 692 (1991) ("The wrongful death cause of action in New York is exclusively statutory, the first such statute having been enacted in 1847."). A wrongful death claim is predicated on a "wrongful act, neglect or default which caused the decedent's death against a person who would have been liable to the decedent by reason of such wrongful conduct if death had not ensued." N.Y. Est. Powers & Trusts Law § 5-4.1(1); *see In re Terrorist Attacks on Sept. 11, 2001*, No. 03-MDL-1570, 2024 WL 3046225, at *2 (S.D.N.Y. June 17, 2024) (quoting same as "the core requirement" of "wrongful death claims"); *see Grosshandels-Und Lagerei-Berufsgenossenschaft v. World Trade Ctr. Props., LLC*, 435 F.3d 136, 140 (2d Cir. 2006) (explaining that New York's wrongful death statute "provide[s] certain individuals with the right to recover for pecuniary loss caused by the wrongful acts of third parties" (citing N.Y. Est. Powers & Trusts Law § 5-4.1)). "The elements of a cause of action to recover damages for wrongful death are (1) the death of a human being, (2) the wrongful act, neglect or default of the defendant by which the decedent's death was caused, (3) the survival of distributees who suffered pecuniary loss by reason of the death of decedent, and (4) the appointment of a personal representative of the decedent." *Est. of*

Richards by Stephens v. City of New York, No. 18-CV-11287, 2024 WL 3607220, at *13 (S.D.N.Y. July 31, 2024) (quoting *Freeland v. Erie Cnty.*, 167 N.Y.S.3d 683, 685 (App. Div. 2022)).

Plaintiff alleges that his wrongful death claim is premised on the alleged "acts of negligence and product liability," (Am. Compl. ¶ 83), which include strict products liability based on manufacturing defect, negligent defective design, negligence, strict products liability based on failure to warn, and breach of implied warranty claims. Plaintiff's wrongful death claim only survives to the extent that any of these causes of action are viable claims for relief. Because the Court finds that Plaintiff's strict products liability based on manufacturing defect, negligent defective design, negligence, strict products liability based on failure to warn, and breach of implied warranty claims are preempted, Plaintiff's wrongful death claim fails. *See Frei v. Taro Pharm. U.S.A., Inc.*, 443 F. Supp. 3d 456, 464, 471 (S.D.N.Y. 2020) (dismissing wrongful death claim because plaintiffs "fail[ed] plausibly to plead a wrongful act on the part of [the defendant]" as their strict liability, negligence, misrepresentation and deception, and fraud claims were preempted or failed to state a claim), *aff'd sub nom. Frei v. Taro Pharm. U.S.A., Inc.*, 844 F. App'x 444 (2d Cir. 2021); *Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179, 190 (E.D.N.Y. 2012) (dismissing wrongful death claim because "the only wrongful acts [p]laintiffs allege that could provide a basis of liability against the [d]efendants are dismissed as preempted under federal law or for a failure to state a plausible claim"); *Tuosto v. Philip Morris USA Inc.*, No. 05-CV-9384, 2007 WL 2398507, at *16 (S.D.N.Y. Aug. 21, 2007) (dismissing wrongful death claim because plaintiff's fraud, concerted action, strict products liability, and negligence claims were dismissed as preempted by federal law or for failure to adequately plead the elements of the claims).

Accordingly, the Court dismisses Plaintiff's wrongful death claim for failure to state a claim.

III. Dismissal with or without prejudice

Defendant argues that "dismissal with prejudice is appropriate because Plaintiff's claims are preempted." (Def.'s Mem. 25.) Plaintiff has not requested leave to replead.

With leave of Court, Plaintiff already "amended [his] [Complaint] to allege a variety of facts" that he asserts "clearly state a plausible cause of action and show that [he] is entitled to the relief requested." (Pl.'s Opp'n 7, 15.) Because Plaintiff's allegations almost plead a negligent defective design claim that could survive preemption, the Court grants Plaintiff leave to replead his negligent defective design claim as narrowly construed in this Memorandum and Order and his wrongful death claim to the extent it is premised on the repleaded negligent defective design claim. *See Broidy Cap. Mgmt. v. Benomar*, 944 F.3d 436, 447 (2d Cir. 2019) ("[I]t is within the sound discretion of the district court to grant or deny leave to amend . . . ."); *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 28 (2d Cir. 2016) (explaining that leave to amend should be "freely give[n] . . . when justice so requires" but may be denied for good reason, including "instances of futility, undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, or undue prejudice to the non-moving party" (alteration in original) (first quoting Fed. R. Civ. P. 15(a)(2); and then quoting *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 126 (2d Cir. 2008))). As to Plaintiff's strict products liability based on manufacturing defect, negligence, strict products liability based on failure to warn, and breach of implied warranty claims and Plaintiff's wrongful death claim to the extent derivative of these claims, the Court finds that granting Plaintiff leave to amend would be futile because Plaintiff has not requested leave to amend a second time, has not indicated that he lacks access to documents necessary to plead a parallel claim, nor has he suggested facts that he would

add to plausibly give rise to nonpreempted claims. The Court therefore dismisses these claims with prejudice. *See Murphy Med. Assocs., LLC v. Yale Univ.*, 120 F.4th 1107, 1009–10, 1115 (2d Cir. 2024) (affirming dismissal of federal and preempted state law claims with prejudice and finding district court did not err in denying further leave to amend where plaintiff "did not file a motion for leave to amend . . . or propose a second amended complaint" and "it appear[ed] beyond doubt that the plaintiffs [could] prove no set of facts in support of their claims which would entitle them to relief" and the "claims fail[ed] as a matter of law" (brackets omitted) (first quoting *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 221 (2d Cir. 2006); and then quoting *In re Lehman Bros. Mortg.-Backed Sec. Litig.*, 650 F.3d 167, 188 (2d Cir. 2011))); *Melendez v. Sirius XM Radio, Inc.*, 50 F.4th 294, 297 (2d Cir. 2022) (affirming dismissal of preempted claims with prejudice and finding "the district court correctly determined that any leave to re-plead would be futile" because plaintiff "failed to articulate any allegations that he could add in a second amended complaint that [would] overcome preemption"); *In re Trib. Co. Fraudulent Conveyance Litig.*, 10 F.4th 147, 166 (2d Cir. 2021) (finding district court did not abuse its discretion in dismissing state law claims with prejudice because defendant "ha[d] not explained what specific facts he would plead to salvage the[] claims"); *City of New York v. Chevron Corp.*, 993 F.3d 81, 103 (2d Cir. 2021) (affirming district court's dismissal of complaint in its entirety with prejudice where the state law claims were preempted by federal common and statutory law); *Nagel*, 2016 WL 4098715, at *9 (dismissing with prejudice plaintiff's preempted strict products liability, failure-to-warn, and negligence claims because plaintiff did not suggest that "he is missing discovery on vital facts about how the defendant deviated from the FDA requirements in the design, manufacture, or testing of the" device at issue); *see also Tillet*, 2023 WL 4704091, at *6 (denying leave to amend preempted claims for strict liability and negligent

design defect and failure to warn against device manufacturers because "there is no set of facts that [p]laintiff could plead that would evade preemption").

IV. Conclusion

For the foregoing reasons, the Court grants Defendant's motion to dismiss. The Court dismisses with prejudice Plaintiff's claims for strict products liability based on manufacturing defect, negligence, strict products liability based on failure to warn, and breach of implied warranty of merchantability on preemption grounds and Plaintiff's wrongful death claim to the extent based on these preempted claims for failure to state a claim. The Court dismisses without prejudice Plaintiff's negligent defective design claim and his wrongful death claim to the extent it is based on the nonpreempted negligent defective design claim and grants Plaintiff thirty days from the date of this Memorandum and Order to replead the two claims in a second amended complaint. If Plaintiff fails to timely file a second amended complaint, the Court will direct the Clerk of Court to enter judgment and close this case.

Dated: March 28, 2025
Brooklyn, New York

SO ORDERED:

/s/MKB
MARGO K. BRODIE
United States District Judge